

REMARKSClaim Amendments

Claims 1, 3-5, 7-15 and 26 were pending in the present application. Applicants have canceled claim 3-5, and claim 12 and amended claims 1 and 11 without prejudice. Support for amended claims 1 and 11 is found throughout the specification and in originally filed claim 1 and 11. Accordingly, upon entry of the instant amendments, claims 1, 7-11, 13-15, and 26 will be pending in this application. No new matter has been added.

Rejections under the Judicially-Created Doctrine of Obviousness-Type Double Patenting

Claims 1-15 and 26 stand rejected under the judicially-created doctrine of obviousness-type double patenting. Claims 1-15, and 26 are said to be unpatentable over the claims of Application No. 09/406,568 (now U.S. Patent No. 6,468,967). Consistent with current Patent Office practice, Applicants elect to defer any action (such as the filing of a terminal disclaimer) until such time as the Examiner has indicated that there is allowable subject matter in the present application.

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1-4, 11, 13-15, and 26 stand rejected under 35 U.S.C. § 112, first paragraph. The Office Action states that the specification, while enabling for methods of administering daptomycin such that it does not cause muscle toxicity, does not reasonably provide enablement for methods of administering daptomycin derivatives, A54145, A54145 derivatives or other lipopeptide antibiotics in such a manner that they

do not cause muscle toxicity. The Examiner states that it is well known in the art that even structurally similar antibiotics can have different modes and ranges of toxicity (Remington's pp. 1176-1213).

Applicants have amended the claims to recite a method of administering daptomycin at a dose of at least 3 mg/kg at a dosage interval that minimizes skeletal muscle toxicity, wherein the daptomycin dose is repeatedly administered at a dosage interval of once every 48 hours to once weekly. Accordingly, Applicants respectfully submit that pending claims 1, 11, 13-15, and 26 are sufficiently enabled by the specification, and request reconsideration and withdrawal of the rejection of these claims under 35 U.S.C. § 112, first paragraph.

CONCLUSION

For the reasons presented above, Applicants respectfully request reconsideration and prompt allowance of all pending claims.


Applicants have filed concurrently herewith a Petition for a three-month extension of time for replying to the Office Action and authorized payment of the required fees under 37 C.F.R. §§ 1.136 (a) and 1.17. The Commissioner is authorized to deduct any deficient amount or credit any surplus amount to Deposit Account No. 50-1986. With the extension, the time for replying is extended up to and including August 26, 2003.

Accordingly, the present submission is timely.

Respectfully submitted,

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